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Intellectual Property Dept.
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EXAMINER	
HELM, CARALYNNE E	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

Office Action Summary	Application No.	Applicant(s)	
	10/567,979	Al-LAMEE ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22* is/are pending in the application.

4a) Of the above claim(s) *10-20 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

To summarize the current election, applicant elected Group I and the species where Formula I is poly(vinylbutyral-co-vinylalcohol-co-vinylacetate) with a Mw from 50,000 to 80,000, and 88% vinylbutyral groups and Formula II is poly(vinylpyrrolidone-co-vinylacetate) with an average Mw of 50,000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding (U.S. Patent No. 7,294,3290 in view of Hsu et al. (U.S. Patent No. 6,340,465) and the Technical Information on Kollidon VA 64 reference (2000).

Ding teaches a drug-containing poly(acetal) based coating for an implantable medical device, where stents are exemplified as envisioned devices (see abstract and column 5 lines 22-30). In particular, Ding teaches a terpolymer of vinyl butyral, vinyl alcohol and vinyl acetate envisioned in the coating composition (see claim 2, column 3 lines 21-27; instant claims 1 and 5). Variants of this polymer have the vinyl butyral constituting about 88% of the polymer backbone, with about 11% vinyl alcohol and the balance vinyl acetate (see column 3 lines 52-54; instant claims 6 and 7). The molecular weight (M_w) of this polymer is taught to be between 40,000 and 250,000 (see column 3 lines 31-32; instant claim 7). “In the case where the claimed ranges ‘overlap or lie inside ranges disclosed by the prior art’ a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed.Cir. 1990)” (see MPEP 2144.05). Here the taught molecular weight range contains the elected range of 50,000 to 80,000 and thereby makes it

obvious (see instant claim 7). Ding goes on to teach particularly envisioned drugs to include within the coating composition and these include both rapamycin and dexamethasone, as well as compounds that inhibit restenosis (see claims 2-3, column 5 lines 51-55, and column 6 lines 26-27 and 32; instant claim 8). An example demonstrates that Ding et al. contemplated the drug to be present in the coating at about 1:2 drug to vehicle (polymer) (see example 5; instant claim 9). Further, Ding teaches that the polymers may be blended with other polymers that include vinyl acetate, but does not specifically teach a copolymer of vinyl pyrrolidone and vinyl acetate (see claim 10, column 4 lines 48-51, and column 5 line 14; instant claim 1).

Hsu et al. teach a coating composition for implantable medical devices that confers lubricity to the device surface (see abstract and column 1 lines 10-11). Hsu et al. go on to teach the inclusion of a polyvinylpyrrolidone-vinyl acetate copolymer in the coating to enhance the lubricity to the coating (see column 3 lines 56-60 and column 9 lines 31-35; instant claim 1). Such a lubricity enhancing compound is exemplified in the coating composition at 0.4% and 0.5% (including solvent) or 43% and 49% (without solvent) (see table 1 one step solution and example 3 solution B; instant claim 2). Since the implantation of a device would be facilitated by it having a lubricious outer surface (e.g. easier and faster implantation), it would have been obvious to one of ordinary skill in the art at the time the invention was made to select a polyvinylpyrrolidone-vinyl acetate copolymer as a particular “other polymer” to use in the invention of Ding and employ it at the taught percentages. Further since polyvinylpyrrolidone-vinyl acetate copolymers were known to be used in coatings of implantable medical devices at the

time of the invention, one of ordinary skill in the art would have had a reasonable expectation of success for its use in the composition of Ding. Ding in view of Hsu et al. does not teach the molecular weight of the polyvinylpyrrolidone-vinyl acetate copolymer or the proportion of monomers present in the polymer.

The Technical Information on Kollidon VA 64 reference teaches a polyvinylpyrrolidone-vinyl acetate copolymer known for use in drug delivery and film forming applications (see page 1 section 1.1, page 7 section 3.1, and page 8 section 3.3). The polymer is taught to have 60% vinylpyrrolidone and 40% vinyl acetate (see page 4 section 1.2; instant claim 3). Further, the molecular weight (M_w) it taught to be between 45,000 and 70,000 (see page 6 section 2.10). The reference does not specifically teach the molecular weight to be 50,000. However, this molecular weight it within the taught range and at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such a parameter as a matter of routine experimentation. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a polyvinylpyrrolidone-vinyl acetate copolymer with a 60:40 ratio of vinylpyrrolidone to vinyl acetate and a molecular weight of 50,000 in the invention of Ding in view of Hsu et a. Therefore claims 1-9 are obvious over Ding in view of Hsu et al. and the Technical Information on Kollidon VA 64 reference.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding in view of Hsu et al. and the Technical Information on Kollidon VA 64 reference as applied to claims 1-8 above, and further in view of Sass (U.S. Patent No. 6,383,215).

Ding in view of Hsu et al. and the Technical Information on Kollidon VA 64 reference make obvious a coating composition with poly(vinylburtyral-co-vinylalcohol-co-vinylacetate) with a M_w from 50,000 to 80,000, and 88% vinylbutyral groups, poly(vinylpyrrolidone-co-vinylacetate) with an average M_w of 50,000, and a bioactive. This modified reference does not teach the inclusion of 17β-estradiol.

Sass teaches that 17β-estradiol is known to inhibit smooth muscle cell growth and is used to inhibit restenosis and in-stent stenosis (see column 2 lines 50-57; instant claim 8). Since Ding teaches the inclusion of compounds that inhibit restenosis in the coating composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 17β-estradiol in the coating composition of Ding in view of Hsu et al. and the Technical Information on Kollidon VA 64 reference. Therefore claims 1-8 are obvious over Ding in view of Hsu et al., the Technical Information on Kollidon VA 64 reference, and Sass.

Response to Arguments

Applicants' arguments, filed March 2, 2009, have been fully considered but they are not deemed to be persuasive regarding the rejection under 35 USC 103(a).

Applicant argues that the references do not provide a motivation for their combination. According to MPEP 2143, "[t]he Courts have made clear that the teaching, suggestion, or motivation test is flexible and an explicit suggestion to combine the prior art is not necessary. The motivation to combine may be implicit and may be found in the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved." Therefore a motivation for combination arising from the general knowledge of one of ordinary skill is sufficient to justify the combination of references. In addition, Hsu et al. teach the desirability of a lubricious surface for medical devices that are inserted into the human body (see column 1 lines 49-65). Hsu et al. then later teach particular polymers that confer lubricity to coatings when included. Ding teaches a medical device that is inserted into the human body often via a small and at times tortuous passageway. Therefore the combination of the lubricity conferring components for medical devices taught by Hsu et al. with the polymeric coating of Ding would have been obvious to one of ordinary skill in the art.

Applicant also argues that the combination of Ding with Hsu et al. destroys the utility of the drug elution taught by Ding. Further applicant states that the coating of Hsu et al. is not a drug eluting coating. This is not accurate since Hsu et al. explicitly teaches the inclusion of drugs in the coatings of their invention (see column 2 lines 24-29). Therefore it was envisioned by Hsu et al. that the polymers used in the coating of their invention were also able to provide for the elution of drugs attached to or contained within them. Based upon these teachings, it is clear that the combination of Hsu et al. with Ding in no way destroys the drug eluting functionality of Ding.

Applicant argues that the use of the terpolymer of Ding in the composition of Hsu et al. with their taught PVP/VA would fail, because the non-crosslinked polymer of Ding would not retain the PVP/VA of Hsu et al. This is not a persuasive argument because non-crosslinked polymer blends are very well known in the art of medical device coatings where "loss" of one polymer from the coating is not an issue, even in the case where some phase separation occurs. Further, entanglement among the polymer chains would sufficiently anchor the PVP/VA polymer in the coatings. Finally, the rejection did not suggest that the polymer of Ding be integrated into the coating of Hsu et al. but instead the converse where the teaching of lubricious polymer coating additives in Hsu et al. was used to lead the selection of an "other polymer" to include in the coating composition taught by Ding.

Applicant also argues features of the invention that are only recited in the specification (e.g. tunable drug release coating). It is noted that the features upon which applicant relies are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Finally applicant argues that the citation of Sass et al. is irrelevant to claims 1-7. These claims require the presence of a bioactive material as recited in claim 1 and required in its dependent claims 2-7. Since Sass et al. teach a stent device with a coating that contains 17β-estradiol, it most certainly is relevant to claims 1-7.

Applicant's arguments with respect to the rejection under 35 USC 112, second paragraph have been fully considered and are persuasive. The rejection of claims 3, 6, and 7 under this statute has been withdrawn.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615